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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/674,733      | 05/02/2001  | Michael Szardcnings  | 1085.0050000/RWE    | 3759             |

1444 7590 12/28/2004

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WASHINGTON, DC 20001-5303

EXAMINER

CHISM, BILLY D

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/674,733

**Applicant(s)**

SZARDENINGS ET AL.

**Examiner**

B. Dell Chism

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22, 24, 27 and 65-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 7-10, 13-20, 24 and 65-78 is/are allowed.
- 6) ☒ Claim(s) 6, 11, 12, 21, 22 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

This Office Action is response to Applicants' papers filed 30 September 2004. The office action mailed from the USPTO on 06 October 2004 is vacated in lieu of the following:

#### **Withdrawal of Objections and Rejections**

The rejections and/or objections made in the prior office action filed 28 January 2004, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments will be addressed to the extent that they pertain to the present grounds of rejection.

#### ***Claim Rejections - 35 USC § 112***

1. (Maintained in part/Necessitated in part) Claims 11-12, 21-22 and 27 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *in vitro* uses of the claimed compounds, does not reasonably provide enablement for *in vivo* uses.

For the reasons set forth in the previous office action, and because the applicants failed to amend claims 11 and 12 to read *in vitro* versus leaving the language open to both *in vivo* and *in vitro*. Claims 21-22 were not amended in a way that overcomes the lack of enablement for *in vivo* use, wherein the specification does not teach the claimed capabilities that would suit the requirements put forth in the previous office action. A product claim that recites an intended use is required to be enabled for such intended use. Claim 27 remains rejected for the same reasons as stated in the previous office action. Although the amendments to 27 served to obviate other rejections, the lack of enablement is maintained for *in vivo* uses.

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2. (Withdrawn) Rejection of claims 1-5, 7-10, 13-20 and 24 are withdrawn as obviated by traversal or amendment. Claims 13-20 depend from claim 9 and comprise intended *in vivo* and *in vitro* uses that are limited to the scope of claim 9 and the compound MS05 therein.
3. (Withdrawn) Rejection of claims 5-8-9 and 27 under 35 U.S.C. 112, second paragraph, for indefiniteness is withdrawn due amendments and arguments by applicants.
4. (New) Claim 6 is rejected for being improper, unclear and indefinite because the compound of general formula (4) is not the same structure if it is optionally modified as claimed in claim 6. For example, the language of claim 1 is closed to the specific embodiments presented in claim 1. However, claim 1 makes no mention of exchanging whole or parts of whole amino acid residues. Furthermore, the claim 6 lacks antecedent basis in claim 1 for the modifications put forth in claim 6. Therefore, the compounds of claim 6 are outside the limitations of claim 1.

### ***Conclusion***

Claims 1-10, 13-20, 24 and 65-78 are free of the art and in allowable form.

Claims 11-12, 21-22 and 27 remain rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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B. Dell Chism

**PATENT EXAMINER**